

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
BROWNSVILLE DIVISION

MARIA DEL VALLE, §
§
Plaintiff, § Civil Action No. B: 11-113
§
v. §
§
PLIVA, INC., ET AL., § Judge Alexander Williams, Jr.
§
§
Defendants. §
§

**PLAINTIFF'S OBJECTIONS TO THE REPORT AND RECOMMENDATION OF
THE MAGISTRATE JUDGE**

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I. STATEMENT OF THE ISSUES TO BE RULED UPON BY THE COURT

This matter comes before the Court on Plaintiffs' Objections to the Report and Recommendation of the honorable Magistrate Judge Ronald Morgan in connection with Defendants Qualitest Pharmaceuticals, Inc.; Vintage Pharmaceuticals, LLC, PLIVA, Inc., ("PLIVA"); and Teva Pharmaceuticals USA's ("Teva") (hereinafter referred to collectively as "Generic Defendants") Motion to Dismiss. [Doc. 57]. The issue to be ruled upon by the Court is whether all of Plaintiff's claims against these generic manufacturers, involving numerous differing theories of liability, are preempted by the Supreme Court's decision in *PLIVA, Inc. v. Mensing*.

In resolving objections to a magistrate's recommendation on a dispositive motion, the district court judge must determine de novo any part of the magistrate judge's ruling that has been properly objected to. Fed. R. Civ. Pro. 72(b)(3). The district judge may accept, reject, or modify the recommended disposition; receive further evidence; or return the matter to the magistrate judge with instructions. *Id.*

II. SHORT STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDING

On October 14, 2011, Generic Defendants filed a Motion to Dismiss asserting that all of Plaintiff's claims are preempted by the U.S. Supreme Court's decision in *Pliva, Inc. v. Mensing*, 564 U.S. ___, 131 S.Ct. 2567 (June 23, 2011). [Doc. 25]. On December 21, 2011, Magistrate Judge Morgan issued his Report and Recommendation that the Motion to Dismiss should be granted, and Plaintiffs suit against these defendants be dismissed with prejudice. [Doc. 57]. Plaintiffs file these Objections to the Magistrate's Report.

III. SUMMARY OF THE ARGUMENT

In his Report, the Magistrate mistakenly found that the “only valid claim” that exists against a prescription pharmaceutical manufacturer for injuries caused by their drug products is a failure-to-warn claim. [Doc. 57, pg. 8]. In doing so, the Magistrate relied on case law supporting the proposition, not that other claims were invalid, but that the learned intermediary doctrine applied to these claims as well. The result is that the Magistrate’s failure to consider Plaintiff’s other claims (for negligence, negligent misrepresentation, fraud, suppression of evidence, breach of warranties, deceptive trade practices and gross negligence) was in error.

Furthermore, the Magistrate’s Report treats all failure-to-warn claims in the same manner, contrary to instruction by the U.S. Supreme Court, and despite the fact that the *Mensing* Court considered only claims that a generic manufacturer should have changed its labeling to provide different or additional warnings than those appearing in the label for the Reference Listed Drug (“RLD”). Likewise, the Report does not make any finding of a Congressional intent to preempt claims such as Plaintiff’s – a necessary requirement when performing a preemption analysis – nor does it identify any conflicting federal law which would have made it impossible for Generic Defendants to comply with duties under Texas law that differ from those considered in *Mensing*.

The Magistrate also erred in finding that Teva’s status as a brand-name manufacturer of metoclopramide does not alter the preemption analysis announced in *Mensing* with regard to this Defendant. Teva’s status as a brand-name manufacturer of metoclopramide (albeit for the oral solution and not the tablet) removed any obstacle present in the federal regulatory scheme to providing additional warnings about metoclopramide. As a result, the Defendant cannot carry its burden of proving that it was impossible to comply with state and federal law.

Finally, the Magistrate also committed error in finding that Plaintiff should not be allowed to amend her Complaint in order to more specifically allege claims the Magistrate determined

were not preempted under *Mensing*. The liberal standard for amendment of pleadings, and the justification provided in the Report for denial of this relief are also in error.

IV. LAW AND ARGUMENT

A. Plaintiff Has Stated Numerous Valid Claims

The Magistrate's Report found that the only valid claims that may be brought against a prescription drug manufacturer under Texas law are for failing to warn the plaintiff's prescribing physician about the drug. [Doc. 57, pg. 7]; citing *Hackett v. G.D. Searle & Co.*, Case No. A-01-CA-399-SS, 2002 U.S. Dist. Lexis 16245, at *7 (W.D. Tex. Jun. 25, 2002). The Magistrate's reliance on *Hackett* in determining that Plaintiff's other theories of liability are not viable is misplaced. Likewise, the other decisions cited in the Magistrate's Report, *In re Norplant*, 955 F.Supp. 700 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999) and *Wyeth-Ayerst Laboratories Co. v. Medrano*, 28 S.W.3d 87 (Tex. App. 2000) do not support the proposition that Plaintiff's other claims are not valid. Rather, these decisions stand for the simple proposition that the learned intermediary doctrine applies to any theory of liability brought against a prescription drug manufacturer. See, *In re Norplant*, 165 F.3d 374, 380 (5th Cir. 1999) ("[t]he only issue ... on appeal is whether the learned intermediary doctrine applies to [plaintiff's] claims"); *see also Ackermann v. Wyeth Pharmaceuticals*, 526 F.3d 203, 208, n.5 (5th Cir. 2008) ("[t]he learned intermediary doctrine applies to both strict-liability and negligence claims"). While the learned intermediary doctrine may apply to Plaintiff's claims against the Generic Defendants, it does not follow that these claims are therefore preempted under the Supreme Court's decision in *Mensing*.

Under Texas law, a prescription drug manufacturer can be held "strictly liable if the drug was not properly prepared or marketed or accompanied by proper warnings." *Murthy v. Abbott Laboratories*, --- F.Supp.2d ----, 2011 WL 5416333 (2011), quoting *Hackett v. G.D. Searle &*

Co., 246 F.Supp.2d 591, 595 (W.D. Tex. 2002) (denying prescription drug manufacturer's motion to dismiss plaintiff's breach of warranty, strict liability and negligence claims). The learned intermediary doctrine is not an affirmative defense. *Ackermann*, 526 F.3d at 207. Rather, under Texas law, the doctrine merely delineates to whom a defendant owes the duty to warn, but is not used to show that the plaintiff has no valid case. *Id* at 207-208, citing *Medrano*, 28 S.W.3d at 94. "Thus, when the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user." *Id* at 208.

As a result, the liability of a prescription drug manufacturer may be predicated on a theory of affirmative misrepresentation, misrepresentation by concealment, falsity, or upon a finding that the drug was "unreasonably dangerous" because "under all the circumstances under which it is marketed, it subjected the Plaintiff to an unreasonable risk of harm." *Crocker v. Winthrop Laboratories, Division of Sterling Drug, Inc.*, 514 S.W.2d 429, 431 (Tex. 1974); *In re Norplant*, 955 F.Supp. at 709. The result is that the Magistrate's finding that the only viable Texas law claim against a prescription drug manufacturer is for a failure to warn is in error.

B. The *Mensing* Court Did Not Hold That All Warning-Based Claims Are Preempted

Contrary to the Magistrate's Report, the Supreme Court in *Mensing* did not determine that *all* failure to warn claims (or product liability claims) against a generic drug manufacturer are preempted by federal law. Rather, the sole issue determined by the *Mensing* Court was whether it was possible for a generic drug manufacturer to unilaterally change its labeling to add or strengthen warnings to differ from those appearing in the label of the Reference Listed Drug ("RLD"). It is clear from the Court's decision that the preemption found to exist applies only to allegations that a generic manufacturer should have unilaterally changed the content of its metoclopramide label to differ from that of the RLD:

“[Plaintiffs] claimed that ‘despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than that indicated on the label,’ none of the Manufacturers had changed their label to adequately warn of that danger.”

“The parties do not dispute that, if these allegations are true, state law required them to use a different, safer label.”

“What is in dispute is whether, and to what extent, generic manufacturers may change their labels *after* initial FDA approval.”

“Taking Mensing and Demahy’s allegations as true, this duty required the Manufacturers to use a different, stronger label than the label they actually used.”

“If the manufacturers had independently changed their labels to satisfy their state-law duty...”

“Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action.”

PLIVA, Inc. v. Mensing, 131 S.Ct. 2567, 2573, 2574, 2577, 2578, 2581. The Court also made clear that it was not making a determination that the state laws at issue actually required a generic manufacturer to change their label, but rather stated that the parties “did not dispute” that the laws of Minnesota and Louisiana required a generic manufacturer to take such action. *Id.*

It is clear that the Court in *Mensing* did not consider the extent to which a generic manufacturer could be held liable for *selling* an unreasonably dangerous product, for accompanying its product with *false information* about potential risks associated with metoclopramide, and for *concealing* important safety information from the FDA, consumers, and the medical community. Both the *Mensing* opinion, and the Solicitor General’s *amicus* brief submitted to the *Mensing* Court (attached hereto as Exhibit A) acknowledge that the issue of whether Generic Defendants could be held liable for placing its metoclopramide into the stream of commerce without adequate instructions for use, and with a label containing false information were not being considered. *Mensing*, 131 S. Ct. at 2588, n.8 (Sotomayor in dissent); Brief for the United States as *amicus curiae*, Ex. A at pg. 25. Given the above, the finding implicit in the Plaintiff’s Objections to Magistrate’s Report and Recommendation

Magistrate's Report, that generic drug manufacturer cannot be held liable for selling a misbranded drug, for concealing important safety information, or for misrepresenting the effect of their drug product is in error.

Recently, the 5th Circuit considered failure-to-warn claims premised on the failure of a medical device manufacturer to fulfill its post-marketing surveillance and reporting duties imposed by FDA regulations, as opposed to a claim premised on the necessity to change the content of the product's label. *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 at 765-766 (5th Cir. 2011). The Court's analysis was guided by the decisions of the Supreme Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which also considered the preemptive effect of federal law on state-law claims against manufacturers of medical devices.

In *Riegel* and *Lohr*, the Supreme Court considered the extent to which an express preemption clause which displaces any state law which would subject a medical device manufacturer to requirements that are “different or in addition to the federal requirement[s].”² *Hughes*, 631 F.3d at 767–768. The Court found that *Riegel* and *Lohr* “make clear that a manufacturer is not protected from state tort liability when the claim is based on the manufacturer’s violation of applicable federal requirements.” *Id* at 767. While noting that the Court’s decision in *Riegel* dictated the dismissal of claims that would “require [defendant] to have included different warnings, labels, or instructions with the device,” the Court reached a different conclusion with respect to the plaintiff’s failure to warn claims premised on the defendants

² As a result the scope of the preemption at issue in *Lohr* and *Riegel* is much broader than the preemptive scope at issue in *Levine* and *Mensing*, where congress expressed its intent not to displace any provisions of state law absent a “positive and direct” conflict.

“failure to report ‘serious injuries’ and ‘malfunctions’ of the device as required by applicable federal regulations.” *Id* at 769.

The court found that to the extent that state law imposed a duty on the manufacturer to provide “reasonable warnings” of the risks associated with its products, that the defendant’s failure to fulfill its postmarketing safety surveillance and reporting obligations would subject it to liability. As stated by the court:

Rather, a failure to warn claim limited to an assertion that the defendant violated a relevant federal statute or regulation is “parallel” to federal requirements as defined in *Riegel*, in which the Court stated that “§360k does not prevent a State from providing a damages remedy for claims premised on violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”

Id (internal citations omitted). In finding that plaintiff’s claims premised on the defendant’s failure to conduct and report required post-marketing surveillance, the court stated that “[a] factfinder could infer that a manufacturer’s failure to provide this information as required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device’s risks.” *Id* at 770-771. Finally, with respect to preemption, the court stated the following:

As we have explained, the doctrine of preemption is designed to foreclose a state cause of action that imposes different or additional requirements on a defendant when compared to federal requirements. The only issue presented to us on this appeal is whether the district court correctly determined that Hughes’ suit is preempted. Thus, [defendant’s] preemption defense only requires us to decide which of Hughes’ state law causes of action are foreclosed under [federal law].

Id at 771.

In its discussion, the 5th Circuit noted that, while post-marketing safety reports were submitted to the FDA, “the FDA then disseminates these reports to the public, and the reports are then relied upon by physicians and authors of medical journals in comparing the relative safety of medical devices.” *Id* at 770, n.5. The same is true for the postmarketing safety reports submitted

by pharmaceutical manufacturers – both brand and generic. To monitor the safety and effectiveness of drug products in the population, the FDA maintains an electronic database referred to as “AERS” (“Adverse Event Reporting System”).³ This database contains all of the adverse event reports submitted to the agency since 1969, when it was created, and the information it contains is publicly available. In addition, individuals may engage a service that will generate a report for a specific drug which summarizes all entries relating to the product in an easily usable fashion. *See, Excerpts of AERS Sample Report, attached as Exhibit B.*⁴ The result is that Generic Defendants’ failure to supply the FDA with information as required by federal law deprived the FDA, the medical community and consumers of important safety related information regarding metoclopramide – information that, had it been known to Plaintiff or her physicians, would have prevented the injuries she sustained.

Furthermore, the FDA has indicated that any manufacturer – generic or branded – may initiate three types of studies to evaluate the risks associated with their drugs once they have been introduced to the general population.⁵ While Generic Defendants would not have had to gain approval from the FDA in order to initiate one of these studies, they would be required to submit the information obtained in these studies as part of their post-marketing reporting requirements, which would in turn be publicly available through AERS. As a result, Defendants’ failure to undertake any effort to study, monitor or report the risks associated with drug products served to give continued validity to the false, inaccurate and misleading information disseminated about metoclopramide. Had adequate information been available, Plaintiff’s injuries could have been

³ The FDA’s website contains a description of how the AERS system operates. *See,* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>

⁴ Also available at <http://www.fda.gov>

⁵ *See Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (2005), pp. 12-17, Attached as Exhibit C (discussing pharmacoepidemiologic studies, surveys, and registries).*

avoided. As acknowledged by the 5th Circuit in *Hughes*, not all failure-to-warn claims require a manufacturer to change the content of their labeling. The Magistrate’s recommendation that all of Plaintiff’s failure-to-warn claims are preempted under *Mensing* is in error.

Finally, the Magistrate’s finding that Defendant Teva’s status as one of the brand-name manufacturers of metoclopramide did not affect the issues before the Court is also in error. While acknowledging that the status of Teva’s metoclopramide oral solution as the RLD rendered it a “brand name holder” for purposes of the Court’s analysis in *Mensing*, the Magistrate found that since Plaintiff only consumed the tablet form of the drug, this fact was immaterial. Plaintiff’s Complaint does not allege that Generic Defendants failed to warn about metoclopramide tablets, nor did any Defendant present any argument that the risks and side effects of the two dosage forms differ in their safety or efficacy - because they do not. Thus, Teva’s status as a brand name manufacturer removed any obstacle imposed by federal regulations on its ability to warn about the effects of metoclopramide – in whatever form it was produced. Having identified no conflict with any federal regulation that would prevent the manufacturer from unilaterally alerting physicians and consumers of the dangers of the drug, Teva cannot claim that *any* of Plaintiff’s claims against it are preempted.

C. Generic Defendants’ Labels Were Not “Satisfactory As a Matter of Law”

In his Report, Magistrate Judge Morgan found that certain “warnings by the generic drug defendants were satisfactory as a matter of law since they matched the brand name warnings and labeling.” [Doc. 57, pg. 14]. The Report cites to no authority for the proposition, and the finding is contrary to the Supreme Court’s decisions in both *Mensing* and *Wyeth v. Levine*, 555 U.S. 555 (2009). In *Levine*, the question considered by the Court was “whether the FDA’s drug labeling judgments ‘preempt state law product liability claims premised on the theory that different

labeling judgments were necessary to make drugs reasonably safe for use.” 129 S.Ct. at 1193. The broad question addressed by the Court in *Levine* stands in stark contrast to the narrow issues presented to the Court in *Mensing*.⁶ In *Levine*, the petitioners argued that tort claims against a pharmaceutical manufacturer were preempted because state court judgments finding a manufacturer liable for injuries caused by their drug products would conflict with the FDA’s determination that the drug was safe and effective for use. *Id* at 563-64. In simple terms, the issue before the Court was whether FDA approval of a prescription drug label rendered the warnings contained therein “adequate as a matter of law.”

The court squarely rejected the manufacturer’s argument, finding that Congress did not intend to preempt *any* tort claims (absent a “positive and direct conflict”) against a drug manufacturer when enacting the FDCA:

As it enlarged the FDA’s powers to “protect the public health” and “assure the safety, effectiveness, and reliability of drugs,” Congress took care to preserve state law. The 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a “direct and positive conflict” with the FDCA. Consistent with that provision, state common-law suits “continued unabated despite … FDA regulation.” And when Congress enacted an express pre-emption provision for medical devices in 1976, it declined to enact such a provision for prescription drugs.

Id at 1195-1196 (internal citations omitted). The *Mensing* Court based its finding of preemption on a finding of a “direct and positive conflict” such as that contemplated in the FDCA’s savings clause, and quoted by the Court in *Levine*. As a generic manufacturer was prohibited by federal law from unilaterally changing the content of its label, a state law seeking to hold it liable for failing to violate this provision of federal law was found to be preempted.

⁶ The questions presented in *Mensing* were whether states were “preempted under the Supremacy Clause of the Constitution from requiring additional safety information on a generic product label where the brand has not changed its label” and whether “the Hatch-Waxman Act preempt[s] state-law-failure-to-warn claims against the manufacturer of a generic drug who’s warnings were ‘the same as’ those the FDA approved for the product’s brand-name equivalent.” *Demahy* Petition for Certiorari, 2010 WL 2325355; *Mensing* petition for certiorari, 2010 WL 638478.

Still, *Mensing* does not indicate that the inability of a generic manufacturer to change the content of its labeling rendered its warnings “adequate as a matter of law.” To the contrary, as stated by the Court in *Levine*:

In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

Id at 1200, 1201-1202 (internal citations omitted). Thus, the Supreme Court in *Levine* found that a jury’s “second-guessing” the determination of safety and efficacy made by the FDA was insufficient justification to find a tort claim preempted by the FDCA. Likewise, in *Mensing*, the Court specifically noted that “[f]ederal law does not dictate the text of each generic drug's label,” -which could render the warnings contained within adequate as a matter of law – “but rather ties those labels to their brand-name counterparts.” *Mensing*, 131 S.Ct. at 2578. The Magistrate’s finding that a generic drug’s labeling is “satisfactory as a matter of law” if it matches the brand-name label is in error. If the branded label contains inadequate warnings or instructions for safe use, a generic that copies the label and warning will still be inadequate. While a generic manufacturer may not be able to alter the content of the information appearing in the drug’s label, that is not the only action that could be taken in order to ensure the safety of consumers, nor is it the only duty imposed upon Generic Defendants by Texas and federal law.

D. Other Federal Law Duties

a. The FDCA and Misbranding

As the Supreme Court has acknowledged, since its inception, the FDCA has “prohibited the manufacture or interstate shipment of adulterated or misbranded drugs” and “supplement[s] the protection of consumers already provided by state regulation and common-law liability.” *Wyeth v. Levine*, 129 S.Ct. at 1195-1196 (2009).

As noted by the Solicitor General in its amicus brief:

A drug is “misbranded” in violation of the FDCA when its labeling is false or misleading, or does not provide adequate directions for use and adequate warnings.

...
The labeling of a prescription drug satisfies federal requirements if it gives physicians and pharmacists sufficient information – including indications for use and “any relevant hazards, contraindications, side effects, and precautions” – to allow those professionals to “use the drug safely and for the purposes for which it is intended.” FDA regulations further establish specific requirements for any prescription drug labeling that “purports to furnish information for use,” “whether or not [the information] is on or within a package from which the drug is to be dispensed [or] distributed.” Among those requirements is warning language that “shall describe serious adverse reactions and potential safety hazards [and] limitations in use imposed by them.”

Under the FDCA, a manufacturer may not introduce into commerce a misbranded drug. 21 U.S.C. 331(a)⁷. The Solicitor General stated that allegations that a generic manufacturer’s drug labeling understated the risks associated with a drug and lacked adequate directions for use (such as appear in Plaintiff’s Complaint), were the equivalent of alleging the drug was misbranded :

In addition to whatever claim those allegations state under state law, they would also establish that petitioners’ metoclopramide products were misbranded under 21 U.S.C. 352(f)(2) because those drugs would lack adequate warnings, and petitioners would have failed to discharge their duty under Section 201.57(e) to seek a revision to their approved labeling in light of newly acquired information not previously considered by FDA.

Id at *30. Taken as true, the allegations appearing in Plaintiff’s complaint also establish that Defendants’ metoclopramide products were misbranded under 21 U.S.C. §352(a) and (j) as well. These regulatory provisions prohibit a manufacturer from selling a drug with a label containing

⁷ The FDCA describes the acts it prohibits to include “[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.”

false and/or misleading information, or that is “dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.”

Neither the Solicitor General’s *amicus* brief or the Court’s decision in *Mensing* addressed the ability of a Plaintiff to assert liability against a generic drug manufacturer for continuing to manufacture and distribute its drug, despite the fact that it is misbranded. In fact, both the Solicitor General’s brief, and the *Mensing* opinion acknowledged that the Plaintiff had not advanced such an argument. *Id* at 25⁸; *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2588 (2011)⁹.

Instead, *Mensing* provides that since only the branded manufacturer had the ability to change the content of a drug’s label prior to the enactment of the FDAAA, this specific action was unavailable to generic manufacturers. Still, the action required of generic and branded manufacturers under the FDCA and FDA regulations (proposing labeling changes and providing adequate information to support the claim) are substantively the same. As noted by the Court in *Levine*, even the CBE provision which allows a brand manufacturer to unilaterally change the content of its label is subject to *subsequent* FDA approval. 129 S.Ct at 1198 (“of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation...”). The only difference identified in *Mensing* between a generic and brand manufacturer was the means available to these manufacturers to fulfill their duties. As the Court in *Mensing* did not even consider whether a generic manufacturer could be held liable under provisions of state law for

⁸ “Drugs with FDA approval are presumptively lawful to sell in commerce. Respondents do not contend otherwise or suggest that petitioners’ drugs simply should not have been available on the market.”

⁹ In its decision below, the Eighth Circuit suggested that the Manufacturers could not show impossibility because federal law merely permitted them to sell generic drugs; it did not require them to do so. See *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (2009) (“The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product”); see also *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000) (describing “a case of impossibility” as one “in which state law penalizes what federal law requires ” (emphasis added)). Respondents have not advanced this argument, and I find it unnecessary to consider.”

selling a misbranded drug, nothing in the opinion indicates that this theory of liability is preempted.

b. Communication of Drug Safety Information

The Court's ruling with respect to Plaintiffs' assertion that Generic Defendants could still be held liable for failing to adequately *communicate* warnings, even if they could not change the content of the warning given seemingly misunderstands Plaintiffs' position. Plaintiffs' Complaint alleges that although the FDA had only approved use of metoclopramide for 12 weeks or less and in spite of their knowledge that numerous patients used the drug for longer periods of time, Generic Defendants failed to disclose (and instead actively concealed) the fact that use of the drug for longer than 12 weeks was unlikely to be reasonably safe. Importantly, as noted by the Supreme Court in *Mensing*, “[i]n 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a label change to add that ‘[t]herapy should not exceed 12 weeks in duration.’” The result is that claims against a generic manufacturer for failing to communicate *this* warning - that had appeared in the label for Reglan/metoclopramide since 2004 – would not implicate the preemption at issue in *Mensing*, where state law required a manufacturer to *change the content* of its label.

The Magistrate's Report seemingly addresses communication of warnings that are different or in addition to those that already appear in the labeling for the RLD. Plaintiff does not dispute that, no matter the means used, a generic manufacturer cannot send “substantial new warning information” or “additional warnings” that do not appear in the label of the RLD without running afoul of federal requirements. The same is not true, however, with regard to the failure of a generic manufacturer to inform physicians and consumers of warnings or information that is

“consistent with, and not contrary to” information appearing in the RLD. *Mensing*, 131 S.Ct. at 2576, citing 21 C.F.R. §201.100(d)(1).

While *Mensing* determined that a generic manufacturer could not send “Dear Doctor Letters” that contained different or additional warnings, the Court did not consider whether a generic manufacturer could send such a letter to alert prescribers to information already appearing in or recently added to the label for a drug, such as the prohibition on long-term use added to the Reglan/metoclopramide label in 2004. In its *amicus* brief, the Solicitor General indicated that it would be entirely acceptable and appropriate for a generic manufacturer to send a Dear Doctor Letter in order to inform consumers and physicians of recent safety related changes in labeling. Ex. A, pg. 18.¹⁰ The Solicitor General further noted that whether a “Dear Doctor Letter” could imply therapeutic differences between the generic and the RLD depended on the *content* of the generic manufacturer’s letter, not the mere fact that the letter had been sent. *Id* at pg. 19. Where such a letter does not contain “substantial new warning information” that does not appear in the FDA-approved labeling, but rather contains only information that is “consistent with and not contrary to” the information appearing in the label of the RLD, no therapeutic difference could conceivably be implied. *Mensing*, 131 S.Ct. at 2576.

Furthermore, numerous courts that have considered claims against a generic manufacturer for failing to communicate information appearing in approved labeling have found that such claims would not be preempted under *Mensing*. See *Keck v. Endoscopy Center of Southern Nevada*, Case No. A57837, Order dated 8/19/2011, attached as Exhibit D (finding that claims that a generic manufacturer should have sent “Dear Doctor Letters” that were “consistent with and not

¹⁰ “To be sure, nothing in the FDCA or FDA’s regulations categorically forbids an ANDA holder from unilaterally sending a DHCP letter. And a DHCP letter can be an appropriate way to bring new information to the attention of medical professionals. But the particular letter respondents envision [containing additional warnings against risks] would only be appropriate in tandem with a corresponding change to the drug’s approved labeling.”

contrary to" FDA-approved labeling were not preempted); *Sacks v. Endoscopy Center of Southern Nevada*, Order dated July 28, 2011, 2011 WL 4915174 (Nevada District Court), attached as Exhibit E (same); *Brasley-Thrash v. Teva Pharmaceuticals USA, Inc.*, CA No. 10-00031 (S.D.Ala), Order dated 9/12/11, attached as Exhibit F (same); *Fisher v. Pelstring, et al.*, 4:09-cv-00252 (D.S.C.), Order dated 9/30/11, attached as Exhibit G (stating that generic metoclopramide manufacturer had "avenues available to it to communicate with physicians about the 2003 and 2004 label changes without seeking FDA approval first,"); *see also In re Reglan/Metoclopramide Litigation*, No. 1997, Order Dated 8/19/2011 (denying preliminary objections of generic manufacturers in 2000 metoclopramide cases), attached as Exhibit H; *Huck v. Trimark, et al.*, Case No. LACV018947 (District Court for Sac County, Iowa), transcript of 8/8/11 hearing (denying PLIVA's Motion to Dismiss based on *Mensing*), attached as Exhibit I.

The result is that *Mensing* has absolutely no relevance to Plaintiffs' claim that Generic Defendants failed to warn doctors that Reglan/metoclopramide was unlikely to be reasonably safe in use beyond 12 weeks. This warning had appeared in the label for the RLD since July, 2004. Thus, during the time that Plaintiff was taking metoclopramide, the FDA-approved labeling indicated that the drug should not be taken for longer than 12 weeks, but Generic Defendants never provided this information to Plaintiff or her prescribing physicians. As outlined in Plaintiffs' Response to Generic Defendants' Motion to Dismiss, there were NUMEROUS means by which the manufacturer could have communicated this information, and as it was explicitly contained in the FDA-approved labeling for the drug, no requirement of federal law prevented them from taking such action.

E. Cases Involving Express Preemption Are Applicable

In its Ruling, the Court found that certain cases cited by Plaintiff in support of her argument were inapplicable to the present case, as the cases dealt with express preemption, and not conflict or impossibility preemption.¹¹ While it is true that some of the cases cited by Plaintiff involve express preemption clauses, the Magistrate's finding that these cases did not consider conflict preemption and were inapplicable to the present case is in error. No matter what form it takes, preemption is fundamentally a question of Congressional intent. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78-79 (1990); *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 299 (1988). While the cases cited in Plaintiff's Response may have involved explicit indication of Congressional intent, the Court in each case considered *both* express preemption *and* implied preemption (such as conflict or impossibility preemption), and found that many claims survived both.

In *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000), the Supreme Court made clear that the existence of an express preemption clause does not preclude the application of principles of implied preemption. Thus, a determination that a Plaintiffs' claims are not expressly preempted, *necessarily* determines that the claims are not subject to conflict preemption as well. To be sure, in *Cipollone*, *Bates*, and *Altria* the Supreme Court explicitly considered preemption of the plaintiffs' state-law claims in the context of *both* express *and* implied preemption, and in each case found that numerous claims were not preempted by either. See *Freightliner Corp., v. Myrick*, 514 U.S. 280, 288-89 (1985) ("just two paragraphs after the quoted passage in *Cipollone*, we engaged in a conflict preemption analysis..."); *Bates v. Dow Agrosciences*, 544 U.S. 431, 458-459 (2005) ("Because we need only determine the ordinary meaning of [the federal statute],

¹¹ Plaintiffs relied primarily on the cases *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008); and *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005).

the majority rightly declines to address respondent's argument that petitioners' claims are subject to other types of preemption."); *Altria Inc., v. Good*, 555 U.S. 70, 87 (2008) ("[a]s an alternative to their express pre-emption argument, petitioners contend that respondents' claim is impliedly pre-empted...").

In *Mensing*, the Court *only* determined that the *action* the plaintiff alleged the generic manufacturers should have taken (changing the content of their labels) was precluded by the "ordinary meaning" of the federal regulation requiring that a generic drug's label match that of the RLD. *Mensing*, 131 S. Ct. at 2580. Nowhere in *Mensing* did the Court find that Congress had any intent to preempt such claims, and, in fact, other Supreme Court precedent identifies the absence of any such intent. As stated by the Court in *Sacks*, "[i]f the Supreme Court had intended to preclude *all* tort claims against generic manufacturers then they would have said so." 2011 WL 4915174.

Finally federal courts have acknowledged the applicability of express preemption cases such as *Bates* to lawsuits such as Plaintiff's:

[c]ommon law rules, such as the ones at issue in [plaintiff's] suit, that require due care to communicate accurate and adequate information to physicians and patients, to avoid misbranding drugs, to refrain from marketing defective products, and to honor express and implied warranties do not 'require that manufacturers label or package their products in any particular way.

Kellogg v. Wyeth, 612 F.Supp.2d 421 (D. Vt. 2008), quoting *Bates*, 544 U.S. at 444. The Court in *Kellogg* also acknowledged that even if a generic manufacturer was unable to change the content of its label, certain claims would still clearly not be preempted:

At the outset, it is important to note that [plaintiff's] claims against the generic drug manufacturers are not exclusively based on failure to add to or strengthen the warnings in FDA-approved labeling for Reglan and generic metoclopramide, or to otherwise notify physicians about the risks of long-term use of the drug. A review of [plaintiff's] product liability claims demonstrates that Counts Four through Six do allege negligence, negligence per se and strict products liability based on a failure to warn. In addition to

claims based on failure to warn or inadequate labeling however, Count Seven asserts breach of express warranties, i.e., that the metoclopramide manufactured by the defendants failed to conform to the representations they made concerning its properties and effects; and Count Eight asserts breach of implied warranties, i.e., that the drug was not of merchantable quality or fit for its common, ordinary and intended use in long-term therapy for GERD. These claims are not based on failure to provide adequate warnings of the risks of long-term use of metoclopramide, and are not in any event preempted by the FDA's drug labeling regulations.

Id at 427-28.

Furthermore, Plaintiff has also alleged that Generic Defendants violated numerous other provisions of federal law in addition to those stated above. These violations include Defendants' failure to perform post-marketing surveillance for their drugs, to ensure the accuracy of statements appearing in their package insert, to review all adverse drug event information, and to report important information relating to the safety of their drug products. These allegations alone are sufficient to defeat a finding that Plaintiff's claims are preempted, and the Magistrate's finding that these failures of Generic Defendants do not subject them to liability are in error.

F. Plaintiff's Should Be Allowed to Amend Their Complaint

In his Report the Magistrate found that a generic manufacturer's failure to include safety information in its labeling that appeared in the labeling for the RLD could place claims against such defendants "outside of the pre-emption described in *Mensing*." [Doc. 57, pg. 12]. Still, the Magistrate recommended dismissing all of Plaintiff's claims without allowing any opportunity to amend her complaint based on the fact that the complaint had already been amended twice previously, and on the basis that Plaintiff's counsel are experienced metoclopramide litigators.

Id. The Magistrate also found that amendment would be futile, as Plaintiff had failed to allege that the failure to include certain warnings in Defendants' labels had caused Plaintiff's injuries.

Id at 13.

Motions to amend made before the expiration of a scheduling order's deadline "should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2); *see also Fahim v. Marriott Hotel Services, Inc*, 551 F.3d 344, 347 (5th Cir. 2008). As noted in the Magistrate's Report, Plaintiff has amended her Complaint twice previously – both times to add or remove parties. Notably, at the time these amendments were made, Plaintiff was not being represented by the "experienced counsel" identified by the Magistrate as being involved in numerous metoclopramide cases. *See* [Docs. 28, 36, 37] (Notice of Appearance and Orders granting admission *pro hac vice* on September 15th and 23rd). The reasons cited by the Magistrate for not allowing Plaintiff to amend her Complaint are directly at odds with Rule 15's direction that leave should be freely given.

Furthermore, the Magistrate's finding that Plaintiff's Complaint does not allege that the failure of Generic Defendants to provide certain safety information in their labeling is an overly narrow construction. Plaintiff has alleged that Generic Defendants failed to warn that metoclopramide was not safe in long-term use, and that they concealed this fact. These allegations are sufficient to encompass the failure of a generic defendant to include statements that "[t]herapy should not exceed 12 weeks in duration" in its label – which federal regulations mandated should have been included since July 2004. In any event, the adequacy of a product's warning is generally a question of fact to be determined by the jury. *McNeil v. Wyeth*, 462 F.3d 364, 368 (5th Cir. 2006). If the revisions to the label for Reglan would have caused Plaintiff's prescribing physician to alter his prescribing habits, then this warning would have been adequate. The Magistrate's finding to the contrary is in error.

Respectfully Submitted this 4th day of January, 2012,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed electronically on November 3, 2011, and is available for viewing and downloading from the ECF system. Notice of Electronic Case Filing has been sent automatically to all parties listed in the Service List in effect on the date of electronic filing, which constitutes service of same, and satisfies the requirements of Fed. R. Civ. P. 5(b)(2)(D).

/s/ Terrence J. Donahue, Jr.
TERRENCE J. DONAHUE, JR.